

# United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FI	LING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
10/636,079	08/06/2003		Janet K. Yamamoto	UF-152FWCD2	1433
23557	7590	06/16/2006		EXAMINER	
SALIWAN	CHIK LL	OYD & SALIWA	CHEN, STACY BROWN		
		SSOCIATION		ART UNIT	PAPER NUMBER
PO BOX 14: GAINESVII		32614-2950	1648	TALER NOMBER	

DATE MAILED: 06/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No.	Applicant(s)	
	Office Action Summary	10/636,079	YAMAMOTO, JA	ANEI K.
	Office Action Summary	Examiner	Art Unit	
		Stacy B. Chen	1648	
۔۔ Period for	The MAILING DATE of this communicates	tion appears on the cover s	neet with the correspondence a	address
A SHC WHICI - Extens after S - If NO p - Failure Any re	PRIENT STATUTORY PERIOD FOR HEVER IS LONGER, FROM THE MAIL sions of time may be available under the provisions of 3 IX (6) MONTHS from the mailing date of this communic period for reply is specified above, the maximum statute to reply within the set or extended period for reply will, ply received by the Office later than three months after dipatent term adjustment. See 37 CFR 1.704(b).	LING DATE OF THIS CON 17 CFR 1.136(a). In no event, howeve cation. bry period will apply and will expire SIX by statute, cause the application to be	IMUNICATION.  r, may a reply be timely filed  ( (6) MONTHS from the mailing date of this ecome ABANDONED (35 U.S.C. § 133).	
Status				
1)⊠ I	Responsive to communication(s) filed o	on <i>12 May <u>2006</u>.</i>		
•	•			
3) 🔲 🤅	Since this application is in condition for	allowance except for form	al matters, prosecution as to the	he merits is
(	closed in accordance with the practice	under <i>Ex par</i> te Quayle, 19	35 C.D. 11, 453 O.G. 213.	
Dispositio	on of Claims			
5)□ ( 6)⊠ ( 7)□ (	Claim(s) 31-36,38-43 and 50-63 is/are a) Of the above claim(s) is/are claim(s) is/are allowed.  Claim(s) 31-36,38-43 and 50-63 is/are claim(s) is/are objected to.  Claim(s) are subject to restriction	withdrawn from considerati	ion.	
Application	on Papers			
10)⊠ T , , ,	The specification is objected to by the End of the drawing(s) filed on <u>06 August 2003</u> Applicant may not request that any objected Replacement drawing sheet(s) including the coath or declaration is objected to be	is/are: a) accepted or b in to the drawing(s) be held in e correction is required if the o	abeyance. See 37 CFR 1.85(a). drawing(s) is objected to. See 37	CFR 1.121(d).
Priority u	nder 35 U.S.C. § 119			
12) [ A a) [ 2	Acknowledgment is made of a claim for All b) Some * c) None of:  1. Certified copies of the priority do  2. Certified copies of the priority do  3. Copies of the certified copies of application from the International see the attached detailed Office action f	cuments have been receiv cuments have been receiv the priority documents hav I Bureau (PCT Rule 17.2(a	ed. ed in Application No e been received in this Nationa )).	al Stage
Attachment	(s) of References Cited (PTO-892)	4) □ In	terview Summary (PTO-413)	
2) Notice 3) Inform	of Draftsperson's Patent Drawing Review (PTO patient Drawing Drawing Drawing Review (PTO patient Drawing Drawi	Pa 0/SB/08) 5) D No	aper No(s)/Mail Date  otice of Informal Patent Application (P	PTO-152)

Application/Control Number: 10/636,079 Page 2

Art Unit: 1648

## **DETAILED ACTION**

1. Applicant's after-final amendment filed May 12, 2006 is acknowledged and entered. Claims 31-36, 38-43 and 50-63 remain pending and under examination. In the final Office action of March 22, 2006, claims 31-36, 38-43 and 50-63 were indicated as allowable. Upon further consideration of the claimed invention, prosecution in this application is reopened in order that the following new rejection may be made.

- 2. The following rejections are either moot or withdrawn:
  - The rejection of claims 37, 42 and 43 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2 and 4 of U.S. Patent No. 5,846,825, is most with respect to cancelled claim 37, and withdrawn with respect to claims 42 and 43 in view of Applicant's filing of a terminal disclaimer, which has been accepted.
  - The rejection of claim 37 under 35 U.S.C. 112, first paragraph, for failing to meet the enablement requirement (with respect to the deposit of certain FIV strains) is moot in view of the cancellation of claim 37.

## Claim Rejections - 35 USC § 112

3. (New Rejection) Claims 31-36, 38-43 and 50-63 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a vaccine composition that induces a protective immune response against two or more subtypes of FIV, comprising an effective amount of an FIV immunogen that minimally includes the FIV envelope glycoprotein,

Application/Control Number: 10/636,079

Art Unit: 1648

does not reasonably provide enablement for a vaccine comprising FIV peptides, proteins, and partial viruses that do not include the FIV envelope glycoprotein. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The claims broadly encompass a vaccine composition that induces protection against FIV infection (of multiple subtypes), comprising an amount of any FIV immunogen. The immunogens include synthetic FIV peptides, natural or recombinant FIV proteins, fragments of said proteins, cell-free whole or partial FIV virus, and cells infected with FIV virus. Applicant's specification is enabling for embodiments that encompass the FIV envelope glycoprotein from each of the at least two different FIV subtypes. Embodiments that do not encompass the envelope glycoprotein from each of the at least two difference subtypes, are not enabled by the specification.

The nature of the invention is the protection of felines against FIV infection by administering a composition that comprises at least two immunogens from at least two FIV subtypes. The state of the art is that dual subtype vaccines against FIV are effective when using embodiments that include the envelope proteins of both subtypes (AIDScience, 2002, Vol. 2, No. 8, pages 1-8, of record). The level of one of skill in the art is high, evidenced by the present inventors and those of the cited literature. The level of predictability in the art is limited when considering the administration of any FIV immunogen to protect against FIV. The level of predictability in the art with regard to embodiments that include envelope protein (such as whole virus, partial virus with envelope, and infected cell lines) increases. The amount of direction provided by the specification is limited to vaccines that include the envelope proteins of two

Application/Control Number: 10/636,079

Art Unit: 1648

subtypes. The working examples are drawn to infected cell lines that protect felines against FIV infection.

Given the breadth of the claims, the state of the art, the level of skill in the art, the level of predictability, the working examples, the direction provided by Applicant, and the nature of the invention, one of skill in the art would not be able to practice the full scope of the invention without undue experimentation. Since the only embodiments that have shown protective capabilities are those that include the envelope protein of two subtypes, one of skill in the art would now know how to vaccinate with embodiments that do not include the envelope protein of two subtypes.

Note that this rejection is over embodiments of the claims that were not previously patented in Applicant's other applications.

#### Conclusion

#### 4. No claim is allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The

Application/Control Number: 10/636,079 Page 5

Art Unit: 1648

examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Ataux B Chen 6/14/06

Stacy B. Chen

Primary Examiner

June 14, 2006